LIBELED: 1–5–60, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for eczema, fungus infections, psoriasis, ringworm, and athletes foot; and 502(f)(2)—the labeling of the article failed to bear a warning that its use should be discontinued if undue or unusual irritation of the skin developed and that frequent or prolonged use or application to large areas of the body may cause serious mercury poisoning.

DISPOSITION: 4–8–60. Consent—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARD

DRUGS FOR HUMAN USE*

6052. Lobie #1 tablets. (F.D.C. No. 43069. S. No. 25–122 P.)

INDICTMENT RETURNED: 9–14–59, S. Dist. Iowa, against Sentral Laboratories, Inc., Des Moines, Iowa, and James H. Roberts, president.

ALLEGED VIOLATION: On 11–25–57, the defendants gave to a firm engaged in the business of shipping drugs in interstate commerce, including *Lobie #1 tablets* supplied by the defendants, an invoice containing a guaranty that the Lobie #1 listed in the invoice was neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On 11–25–57, the defendants sold, invoiced, and shipped a quantity of *Lobie #1 tablets*, which were adulterated, to the holder of the guaranty at Council Bluffs, Iowa.

LABEL IN PART: (Drum) "50,000 Lobie # 1 Each tablet contains: dl–Desoxyephedrine Hcl. 4 mg. Thyroid 1 gr. Atropine Sulfate 1/360 gr. Aloin ¼ gr."

CHARGE: 501(c)—the strength of the article differed from that which it purported and was represented to possess, namely, 4 milligrams of dl–desoxyephedrine hydrochloride in each tablet, since each table of the article contained more than 4 milligrams of dl–desoxyephedrine hydrochloride.

PLEA: Guilty.

DISPOSITION: 12–3–59. Fines were assessed in the amount of $2,500 against the corporation and $1,000 against the individual, plus costs.

6053. Procaine hydrochloride injection. (F.D.C. No. 43327. S. Nos. 48–543 P, 48–822 P.)

QUANTITY: 13,045 vials and 840 pkgs., 12 vials each, at San Francisco, Calif., in possession of Allied Biochemical Laboratories.

SHIPPED: Procaine hydrochloride was shipped on 1–29–59, from St. Louis, Mo.

LABEL IN PART: (Vial) "30 cc. Sterile Procaine Hydrochloride Injection USP 1% [or "2%"]."

RESULTS OF INVESTIGATION: The *procaine hydrochloride injection* was manufactured by the dealer from the procaine hydrochloride which was shipped as described above. Examination of the article showed that the pH (acidity) of procaine hydrochloride was less than 3.3, whereas the United States Pharmacopeia requires that the pH of *procaine hydrochloride injection* be between 3.3 and 5.5.

*See also Nos. 6041, 6043, 6045.

LIBELED: 8-4-59, N. Dist. Calif.

CHARGE: 501(b)—while held for sale, the quality of the article fell below the standard for *procaine hydrochloride injection* set forth in the United States Pharmacopeia; and 502(a)—the label statement "Procaine Hydrochloride Injection USP" was false and misleading.

DISPOSITION: 10-5-59. Default—destruction.

6054. Del-Caps timed disintegration capsules. (F.D.C. No. 42794. S. No. 45-496 P.)

QUANTITY: 8 1,000-capsule btls. at Tulia, Tex.

SHIPPED: 9-17-58, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: "Del-Caps 15 Timed Disinegration Capsule * * * Each Capsule Contains Dextro Amphetamine Sulfate 15 mg. * * * in a special base that provides for the disintegration of the contents throughout a period of 6-10 hours. * * * 3565 Manufactured by Delmar Pharmacal Corp. 333 Columbia Street, Rensselaer, New York."

RESULTS OF INVESTIGATION: Analysis showed that each capsule contained 15 mg. of dextro-amphetamine sulfate, 77 percent of which was released in two hours.

LIBELED: 2-2-59, N. Dis. Tex.; libel amended 5-12-59.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it purported and was represented to possess since it failed to distintegrate at a uniform rate over a 6-10 hour period; and 502(a)—the label statement "Each capsule contains Dextro Amphetamine Sulfate 15 mg. * * * in a special base that provides for the disintegration of the contents throughout a period of 6-10 hours" was false and misleading.

DISPOSITION: 1-15-60. Default—destruction.

DRUGS FOR VETERINARY USE

6055. Clotin. (F.D.C. No. 42878. S. No. 53-904 P.)

QUANTITY: 10 cases, 12 tins each, at Springdale, Ark.

SHIPPED: 10-29-58, from Omaha, Nebr., by Gland-O-Lac Co.

LABEL IN PART: (Tin) "Gland-O-Lac 2 Lb. 6 oz. (1.25 Kilos) CLOTIN A stabilized soluble Vitamin K effective without the addition of bile salts, for the prevention of Vitamin K deficiency in poultry and for the correction of hemmorrhagic disease due to such deficiency. Active Ingredient: Menadione Sodium Bisulfite, U.S.P. Each level teaspoonful (3 grams) contains 8.25 milligrams equal to 0.275%. Gland-O-Lac Company, Omaha, Nebr."

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less than the declared amounts of menadione sodium bisulfite.

LIBELED: 3-9-59, W. Dist. Ark.

CHARGE: 501(e)—when shipped, the strength of the article differed from that which it purported and was represented to possess.

DISPOSITION: 8-4-59. Default—destruction.

6056. Medicated poultry feed. (F.D.C. No. 43058. S. Nos. 7-592 P, 7-887 P, 7-964 P.)

INFORMATION FILED: 12-4-59, Dist. Mass., against H. K. Webster Co., a corporation, Lawrence, Mass., and Walter N. Webster, vice president and treasurer of the corporation.